UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,711	12/21/2001	Akira Imaizumi	217576US0	6895

38108 7590 04/20/2004

AJINOMOTO CORPORATE SERVICES, LLC
INTELLECTUAL PROPERTY DEPARTMENT
1120 CONNECTICUT AVE., N.W.
WASHINGTON, DC 20036

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,711	IMAIZUMI ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 6 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 12/23/2003, have been fully considered but they are not persuasive. Applicant's position is that the current claim amendments overcome the written description rejection, where the claims are limited to Escherichia coli, an inactivated RMF protein, and an L-amino acid. The Examiner respectfully disagrees for reasons of record as supplemented below.

MPEP §2111 states that claims must be given their broadest reasonable interpretation consistent with the specification and that such interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. The claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims.

Accordingly, the claims are genus claims that are directed toward any method for making an L-amino acid by culturing an Escherichia coli bacterium having any mutation to any gene of any nucleotide sequence and structure encoding any RMF protein of any amino acid sequence and structure or any mutation to any controlling sequence of rmf gene of any nucleotide sequence and structure, where the resulting RMF protein is inactive.

The claims encompasses a highly variant genus of genes with widely differing structural, chemical, and physical characteristics encoding any RMF protein of any amino acid sequence and structure including yet to be discovered genes from biological sources encoding RMF proteins. Furthermore, the genus is highly variable because a significant number of structural

differences between genus members is permitted.

The specification provides a written description of a transformed E.coli host cell containing an inactivated E.coli rmf gene (generated by crossover PCR) which is used in the recombinant production of acid phosphatase and L-lysine (Examples 2 and 3). However, the specification does not provide the specific SEQ ID NO: of the rmf gene. The specification does not provide additional species of rmf genes and encoded RMF proteins.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

4. Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments filed 12/23/2003, have been fully considered but they are not persuasive. Applicant's position is that the current claim amendments overcome the written enablement rejection, that source materials for the mutated rmf gene is enabled since applicants have deposited an L-lysine producing strain under the Budapest Treaty, the rmf gene asserted to be known, and methods to inactivate genes are known. The Examiner respectfully disagrees for reasons of record as supplemented below.

The claims do not recite the L-lysine producing strain described by applicants, and thus the claims cannot be interpreted as being limited to the said strain described in the specification for the reason explained above for MPEP §2111.

Accordingly, the nature and breadth of the claims encompass any method for making an L-amino acid by culturing an Escherichia coli bacterium having any mutation to any gene of any nucleotide sequence and structure encoding any RMF protein of any amino acid sequence and structure or any mutation to any controlling sequence of rmf gene of any nucleotide sequence and structure, where the resulting RMF protein is inactive. While the E.coli rmf gene has been published, the claims encompass any rmf genes with widely differing structural, chemical, and physical characteristics encoding any RMF protein of any amino acid sequence and structure including yet to be discovered genes from biological sources encoding RMF proteins.

The specification provides a guidance for transformed E.coli host cell containing an inactivated E.coli rmf gene (generated by crossover PCR) which is used in the recombinant production of acid phosphatase and L-lysine (Examples 2 and 3). However, the specification does not provide the specific SEQ ID NO: of the rmf gene.

Teaching regarding searching and screening for rmf genes from different biological sources is not guidance for making the invention encompasses any rmf gene of any structure and

nucleotide sequence. Thus, searching for the biological source of the rmf gene, the nucleotide sequence of the rmf gene and amino acid sequence of the RMF protein is undue and well outside the realm of routine experimentation and predictability in the art of success is extremely low since no specific SEQ ID NO has been disclosed for the rmf gene. The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific genetic modification and nucleotide/amino acid sequence of the "controlling sequence of rmf gene" and the nucleotide/amino acid sequence of the RMF protein. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the phrase "controlling sequence of rmf gene" renders the claims vague and indefinite because the identity, specific structure, and nucleotide sequence of the "controlling sequence of rmf gene" is not known and not recited in the claims. Claim 6 which depend from claim 1 is also rejected because claim 6 does not correct the defect of claim 1.

Conclusion

7. No claim is allowed.

8. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600